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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/628,472	07/31/00	WOLBER	P 10003511-1

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EXAMINER	
FORMAN, B	
ART UNIT	PAPER NUMBER
1655	5

DATE MAILED: 10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/628,472	Applicant(s) WOLBER ET AL.	
	Examiner BJ Forman	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Notice re Copyright NA Sq Rules

DETAILED ACTION

1. Applicant's election without traverse of Group I, Claims 1-15, filed 6 August 2001 in Paper No. 4 is acknowledged. Claims 16-20 are withdrawn from further consideration.

Claims 1-15 are discussed below.

Specification

2. A substitute specification including the claims is required pursuant to 37 CFR 1.125(a) because the upper margin is too small such that when holes are punched in the top, the first line of text is not legible.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Claim Objections

3. Claim 1 is objected to because of the following informalities:

a. Claim 1 is objected to because the recitation "mixture of a nucleic acids" wherein "a" is incorrectly placed before "nucleic acids".

b. Claim 8 is objected to because the recitation "said recognition domain is a recognized by a restriction endonuclease" wherein "a" is incorrectly placed before "recognized".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-4, 14 and 15 are indefinite in Claim 1 for the recitation "contacting said array of single-stranded probe nucleic acids....under hybridization condition" because it is unclear whether the recitation is a method step of contacting or hybridization. It is suggested that Claim 1 be amended to clarify e.g. replace "contacting" with "hybridizing" and/or to recite a method step of hybridizing.

b. Claims 1-4, 14 and 15 are indefinite in Claim 1 for the recitation "subjecting said template array.....to primer extension reaction conditions under conditions sufficient to produce said mixture of nucleic acids" because it is unclear whether the recitation is a method step of primer extension. It is suggested that Claim 1 be amended to recite positive and active method steps to clearly define the invention e.g. delete "conditions under conditions sufficient".

c. Claims 5-9 are indefinite in Claim 5, line 2, for the recitation "each distinct constituent oligonucleotide" because the recitation lacks proper antecedent basis in the claim which recites "distinct deoxyribo-oligonucleotide". It is suggested that Claim 5 be amended to provide proper antecedent basis and to clarify e.g. delete "constituent".

d. Claims 5-9 are indefinite in Claim 5 in the recitations "recognition domain" and "functional domain" because it is unclear what constitutes and differentiates the domains and

because it is unclear what the "recognition domain" recognizes and what function the "functional domain" performs. It is suggested that Claim 5 be amended to clarify e.g. define "recognition domain" and "functional domain".

e. Claims 14 and 15 are each indefinite in the recitation "the assay according to Claim 1" because "assay" lacks proper antecedent basis in Claim 1. It is suggested that both Claims 14 and 15 be amended to provide proper antecedent basis e.g. replace "assay" with "method".

f. Claim 14 is indefinite in the recitation "target nucleic acids" because the recitation lacks proper antecedent basis in Claim 1. It is suggested that the claim be amended to provide proper antecedent basis e.g. replace "target nucleic acids" with "nucleic acids complementary to said constant domain".

g. Claim 15 is indefinite in the recitation "washing unbound away from the surface of said array" because "target" and "surface" lack proper antecedent basis in Claim 1. It is suggested that the claim be amended to provide proper antecedent basis e.g. replace "target" with "nucleic acids complementary to said constant domain" and to replace "the" with "a".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 10-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Cantor et al. (U.S. Patent No. 5,795,714, issued 18 August 1998).

Regarding Claim 1, Cantor et al. disclose a method for producing a mixture of nucleic acids comprising: providing an array of distinct single-stranded probe nucleic acids, contacting said array with nucleic acids complementary to said constant domain under hybridization conditions whereby a template array of overhang comprising duplex nucleic acids is produced, wherein each overhang comprising duplex of said array comprises a double-stranded region and a single-stranded variable region overhang; subjecting said template array to primer extension to produce a mixture of nucleic acids (Column 13, line 41-Column 14, line 22).

Regarding Claim 2, Cantor et al. disclose the method wherein said mixture of nucleic acids is a mixture of deoxyribo-oligonculeotides i.e. DNA (Column 6, lines 43-47).

Regarding Claim 3, Cantor et al. disclose the method wherein said constant domain comprises a linker domain (Column 15, lines 21-28).

Regarding Claim 4, Cantor et al. disclose the method wherein said step (c) comprise in vitro transcription i.e. enzymatically extending the nucleic acids using the probe as a template (Column 14, lines 16-19).

Regarding Claim 10, Cantor et al. disclose a method of making a population of target nucleic acid molecules from an initial mRNA sample comprising: generating a mixture of nucleic acids according to the method of Claim 1 (Column 4, lines 48-61); employing said mixture as primers in a target generation step in which target nucleic acids are produced i.e. to create duplicate arrays (Column 4, lines 48-50) wherein the nucleic acids are RNAs (Column 6, lines 43-47).

Regarding Claim 11, Cantor et al. disclose the method wherein the target generation step comprises template driven primer extension (Column 4, lines 57-58).

Regarding Claim 12, Cantor et al. disclose the method wherein said target generation step produces labeled target nucleic acids (Column 9, lines 28-50).

Regarding Claim 14, Cantor et al. disclose the method of Claim 1 wherein the nucleic acids are labeled (Column 9, lines 1-27).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 5-9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor et al. (U.S. Patent No. 5,795,714, issued 18 August 1998) and Dattagupta et al. (U.S. Patent No. 4,734,363, issued 29 March 1988).

Regarding Claim 5, Cantor et al. teach a method for producing a mixture of a plurality of distinct deoxyribo-oligonucleotides of differing sequence wherein each oligonucleotide comprises a different variable region (Column 7, lines 35-65) comprising: providing an array of a plurality of surface immobilized single stranded probes wherein each probe on the array is described by the formula L-R+F-cV-5' wherein L is an optional linker domain (Column 15, lines 21-28); R+F is the constant domain and cV –5' is the random domain (Column 14, lines 8-16); contacting the array under hybridizing conditions with a population of nucleic acids complementary to the constant domain whereby an overhang duplex nucleic acid is produced; and subjecting the duplex nucleic acids to primer extension whereby a mixture of oligonucleotides of differing sequence is produced (Column 14, lines 16-27). Cantor et al. do not each the constant domain comprises a recognition domain and a functional domain. Dattagupta et al. teach a similar method for producing a mixture of distinct deoxyribo-oligonucleotide wherein the a plurality of single-stranded probes having the formula: A-B-C-5' wherein is A recognition domain, B is functional domain and C is a variable domain; contacting

the probes with nucleic acids having the formula A' B'; and subjecting the overhang duplex to primer extension to thereby produce a plurality of nucleic acids (Column 4, lines 27-53) wherein the functional + recognition domains function to recognize the target sequence and transcription initiation site (Abstract). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the constant domain of Cantor et al. with the functional + recognition domains as taught by Dattagupta et al. to thereby provide target recognition and transcription initiation for the expected benefit of efficient and specific transcription as taught by Dattagupta et al. (Column 3, lines 33-40).

Regarding Claim 6, Cantor et al. teach the linker domain of 0 bases (Column 15, lines 21-27).

Regarding Claim 7, Dattagupta et al. teach the similar method wherein the functional domain is an RNA polymerase promoter domain (Column 5, lines 22-27).

Regarding Claim 8, Cantor et al. teach the method wherein the recognition domain is recognized by a restriction endonuclease (Column 15, lines 29-39).

Regarding Claim 9, Cantor et al. teach the method wherein said step (c) comprise in vitro transcription i.e. enzymatically extending the nucleic acids using the probe as a template (Column 14, lines 16-19).

Regarding Claim 13, Cantor et al. teach a method of generating a set of target nucleic acids according to the method of Claim 10; contacting said set of nucleic acids with nucleic acids under hybridizing condition; and detecting the presence of target nucleic acids hybridized to nucleic acids i.e. the generated nucleic acids are free in solution and hybridized to other nucleic acids for detecting the nucleic acids (Column 4, lines 48-65). Cantor et al. do not teach the nucleic acids in solution are contacted with an array of probes. However, It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the hybridization of Cantor et al. by hybridizing the generated nucleic acids to probes on an array to thereby detect the generated sequences using positional screening for the

expected benefit of rapidly and accurately the sequence of the nucleic acid generated as taught by Cantor et al. (Column 4, lines 11-15).

Regarding Claim 15, Cantor et al. teach the method of Claim 1 for producing a mixture of nucleic acids comprising: providing an array of distinct single-stranded probe nucleic acids, contacting said array with nucleic acids complementary to said constant domain under hybridization conditions whereby a template array of overhang comprising duplex nucleic acids is produced, wherein each overhang comprising duplex of said array comprises a double-stranded region and a single-stranded variable region overhang; subjecting said template array to primer extension to produce a mixture of nucleic acids (Column 13, line 41-Column 14, line 22) but they do not specifically teach said method further comprises washing unbound target away from the surface of the array. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teaching of Cantor et al. by further washing unbound target from the surface of the array for the obvious benefit of eliminating non-specific sequences and reducing background hybridizations.

Requirement to Comply with Nucleic Acid Sequence Rules

10. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given A PERIOD OF TIME WHICH IS CO-EXTENSTIVE WITH THE TIME TO REPLY TO THE ABOVE OFFICE ACTION within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
October 1, 2001

W. Gary Jones
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10/1/01